



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,121	05/02/2001	Robert C. Krall	MP/155	6524

7590 02/03/2004

W. L. Gore & Associates, Inc.
551 Paper Mill Road
P.O. Box 9206
Newark, DE 19714-9206

EXAMINER

SCHAETZLE, KENNEDY

ART UNIT	PAPER NUMBER
----------	--------------

3762

DATE MAILED: 02/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/848,121

Applicant(s)

KRALL ET AL.

Examiner

Kennedy Schaetzle

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-6, 8-12, 15-21, 42-47, 50 and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Soukup et al. (Patent Application Publication No. 2002/0147486).

Regarding claim 1, Soukup et al. disclose an implantable defibrillation lead comprising a coiled defibrillation electrode 306 with a cover of ePTFE 308 at least partially surrounding the coiled electrode. The expandable PTFE is inherently non-conductive in a dry state and conductive when implanted to provide effective conduction of a defibrillation electrical charge (note paragraph 0035). The cover is recited as having a thickness of preferably less than 25 microns, or 0.025 mm (note par. 0037).

Regarding claims 11 and 12, the examiner considers the lead of Soukup et al. to inherently meet the recited limitations by nature of its similar construction. Even with both ePTFE layers 308 and 310 covering the electrode, the thickness of the porous polymer would still be preferably less than 0.05 mm –well within the applicants' recited range.

Concerning claim 15, note the embodiment shown in Fig. 9 that allows for easy extraction of the lead.

Concerning claims 16-20, the examiner once again considers the limitations to be inherent in the device of Soukup et al. given the fact that similar materials, of similar thicknesses, are used on similar leads. Furthermore the applicants' attention is invited to paragraph 0051 of Soukup et al. that discloses that gas build-up is effectively

Art Unit: 3762

reduced about the electrode. Such a reduction in electrode bubble formation is disclosed by the present applicants as a means for preventing mechanical disruption, thus resulting in less fatigue.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Soukup et al..

Regarding claim 7, Soukup et al. teach to design a cover that is as thin as possible and preferably less than 0.025 mm, in order to limit the overall lead size and enhance wetting. Obviously 0.01 mm meets this desired condition. Given the fact that Soukup et al. lead the manufacturer to produce covers as thin as possible, and given the fact that the applicants have not recited any criticality or asserted any particular advantage in covers of 0.01 mm in thickness as opposed to covers from 0.1 to 0.025 mm in thickness and thinner, those of ordinary skill in the art would have seen the obviousness of employing covers of thicknesses of less than about 0.01 mm.

5. Claims 13, 14, 22-41, 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soukup et al. in view of Carson (Pat. No. 5,931,862).

Regarding claims 13, 22 and 48, all the comments made in the rejection of claim 1 apply here as well, wherein Soukup et al. disclose all of the recited elements with the exception of the wetting agent. Carson, however, teaches that medical leads with coverings of ePTFE may incorporate a wetting agent in order to facilitate the filling of the pores and thus render faster implant times, reducing the risk of infection, bleeding and tissue dehydration (col. 1, lines 14-38). Any artisan desiring to take advantage of these clearly defined benefits would have therefore seen the obviousness of employing a wetting agent in the apparatus of Soukup et al..

Concerning claims 14, 34 and 49, Carson discloses that polyvinyl alcohol (PVA) may be employed as a suitable wet-out agent (col. 6, lines 10-20). Clearly PVA is a well-known wetting agent to those of ordinary skill in the medical lead arts. The courts have long recognized that the selection of a known material based on its suitability for its intended use was considered obvious (see *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945)).

Concerning claims 23-27, 32, 33, and 35-40 note the rejection of similar claims above.

Response to Amendment

6. The declaration filed on November 24, 2003 under 37 CFR 1.131 has been considered but is ineffective to overcome the Soukup et al. reference.

The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Soukup et al. reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). No evidence has been submitted to show that the applicants had in their possession prior to the date of the Soukup et al. reference, an implantable defibrillator lead with an electrode cover having a thickness of less than about 0.13 mm. The applicants give great criticality to the thickness of the electrode cover in the present application. Absent any such evidence, the rejection under Soukup et al. will remain.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

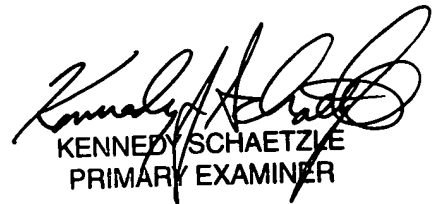
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0858.

KJS
February 2, 2004


KENNEDY SCHAETZLE
PRIMARY EXAMINER